August 6, 2021

ACHIMHAI Medical Corporation
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200
Irvine, California 92620

Re: K200193
Trade/Device Name: Kisses Plus Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 23, 2021
Received: July 6, 2021

Dear Priscilla Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200193

Device Name
Kisses Plus Implant System

Indications for Use *(Describe)*
The Kisses Plus Implant System is indicated for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
The Kisses Plus Implant System is for single and two stage surgical procedures. It is for delayed loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary
# (K200193)

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 8/6/2021

## 1. Submitter

ACHIMHAI Medical Corporation
28, Namyang-ro, 930beon-gil, Namyang-eup
Hwaseong-si, Gyeonggido, Republic of Korea, 18255

## 2. U.S Agent/Contact Person

Priscilla Chung
LK Consulting Group USA, Inc.
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## 3. Device

- Trade Name: Kisses Plus Implant System
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Implant
- Product Code: NHA
- Classification regulation: 21CFR 872.3630

## 4. Predicate Device:

- **Primary Predicate Device:**
  NobelActive Multi Unit Abutment by Nobel Biocare AB (K072570)

- **Reference Predicate Device:**
  Multi Unit Abutment Plus by Nobel Biocare AB (K161416)
  SimpleLine II Abutment System by Dentium (K112045)
  Biogensis Implant System-Kisses by Biogenesis Co., Ltd. (K142813)
  Kisses Plus Implant System by ACHIMHAI Medical Corporation (K172630)

## 5. Description:

This 510k is to add the following abutments to Kisses Plus Implant System.

| Type |
|---|
| Multi Straight Abutment |
| Multi Angled Abutment |
| CCM Abutment |
| Multi CCM Abutment |

- Multi Straight Abutment

  The Multi Straight Abutment is not used alone but used with a Multi CCM Abutment. The Multi CCM Abutment is fastened on the top of the Multi Straight Abutment. The Multi Straight abutment is compatible with every size of fixtures cleared under K142813 and K172630. The abutment is made of Ti 6Al 4V ELI (ASTM F136).

  Dimension ranges:

| | |
|---|---|
| Length | 8.8 ~ 12.5mm |
| Diameter | 4.8mm |
| Gingival height | 1.5 ~ 4.5mm |
| Angulation | - |
| Post height | 2.2mm |

- Multi Angled Abutment

  The Multi Angled Abutment is not used alone but used with a Multi CCM Abutment. The Multi CCM Abutment is fastened on the top of the Multi Angled Abutment. The Multi Straight abutment is compatible with every size of fixtures cleared under K142813 and K172630. The abutment is made of Ti 6Al 4V ELI (ASTM F136).

  Dimension ranges:

| | |
|---|---|
| Length | 6.44 ~ 7.93mm |
| Diameter | 4.8mm |
| Gingival height | 2.5 ~ 4.5mm |
| Angulation | 17 ~ 30° |
| Post height | 2.2mm |

- CCM Abutment

The is one of the final abutments to be coupled to the fixture which will be positioned in the bone through gingiva. It forms a set with its abutment screw. This abutment is designed for casting with dental alloy in the lab. The plastic part is burned out during casting. The CCM Abutment is compatible with every size of fixtures cleared under K142813 and K172630. The abutment is made of Co Cr Mo (ASTM F1537).

Dimension ranges:

| | |
|---|---|
| Length | 15.1 ~ 17.05mm |
| Diameter | 4.0 ~ 4.5mm |
| Gingival height | 1.0mm |
| Angulation | - |
| Post height | - |

- Multi CCM Abutment

The Multi CCM Abutment is used with the multi straight abutment and the multi angled abutment. This is one of the final abutments to be coupled to the fixture which will be positioned in the bone through gingiva. It forms a set with its abutment screw. The CCM Abutment is compatible with every size of fixtures cleared under K142813 and K172630. The abutment is made of Co Cr Mo (ASTM F1537).

Dimension ranges:

| | |
|---|---|
| Length | 15.0mm |
| Diameter | 4.8mm |
| Gingival height | - |
| Angulation | - |
| Post height | - |

The following screws are used with the abutments.

All of the screws below were cleared under K172630.

| Type | Model Names |
|---|---|
| Abutment Screw | KAS16 |
| | ATAS20 |

We intend to add the following abutment screws to the Kisses Plus System.

| Type | Model Names |
|---|---|
| Multi Abutment Screw | KAS-16M |
| | AAS-20M |

## 6. Indication for use:

The Kisses Plus Implant System is indicated for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
The Kisses Plus Implant System is for single and two stage surgical procedures. It is for delayed loading.

## 7. Basis for Substantial Equivalence

**Multi Straight Abutment & Multi Angled Abutment**

| | Subject Device | Primary Predicate Device | Reference Predicate Device |
|---|---|---|---|
| 510(K) Number | K200193 | K072570 | K161416 |
| Device Name | Kisses Plus Implant System | NobelActive Multi Unit Abutment | Multi Unit Abutment Plus |
| Manufacturer | Achimhai Medical Corporation | Nobel Biocare AB | Nobel Biocare AB |
| Type | Internal | Internal | Internal |
| Indications for Use | The Kisses Plus Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.<br><br>The Kisses Plus Implant System is for single and two stage surgical procedures. It is for delayed loading. | NobelActive Multi Unit Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. | The Multi-unit Abutment Plus is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. |
| Principle of Operation | The abutments are to be coupled to the fixtures to make temporary or final prosthesis. | The abutments are to be coupled to the fixtures to make temporary or final prosthesis. | The abutments are to be coupled to the fixtures to make temporary or final prosthesis. |
| Multi Straight Abutment | | | |
| Design & Size Range |  <br>Non-Hex<br>Diameter: 4.8mm |  <br>Non-Hex<br>Diameter: 4.8mm<br>Gingival Height: 1.5-4.5mm |  <br>Non-Hex<br>Diameter: 4.8mm<br>Gingival Height: 1.5-4.5mm |

| | | | |
|---|---|---|---|
| | Gingival Height: 1.5-4.5mm | | |
| Intended Use | Screw retained restoration | Screw retained restoration | Screw retained restoration |
| Material Composition | Ti 6Al 4V ELI(ASTM F136) | Ti 6Al 4V ELI(ASTM F136) | Ti 6Al 4V ELI(ASTM F136) |
| Surface Treatment | No | No | No |
| Sterile | No | No | No |

Substantial Equivalence Discussion

The subject Multi Straight Abutment is substantially equivalent to the predicate devices in terms of indications for use and technical characteristics. The indications for use statement of the subject device is identical to our company's own reference device, K172630. In addition, the indications for use of the primary predicate, which states that it is "intended for use as an aid in prosthetic rehabilitation", is inherent to the overarching system.

They are made of the same material. The size range of the predicate devices encompasses the size range of the subject device. The design is slightly different as the predicate device has more grove at the top, but the difference is minor and does not raise a question in substantial equivalence.

| Multi Angled Abutment | | | |
|---|---|---|---|
| <Multi Angled Abutment> Design & Size Range |  <br>Hex<br>Width: 4.8mm<br>Gingival Height: 2.5-4.5mm<br>Angle: 17° - 30° |  <br>Hex<br>Width: 4.8mm<br>Gingival Height: 2.5-4.5mm<br>Angle: 17° - 30° |  <br>Hex<br>Width: 4.8mm<br>Gingival Height: 2.5-4.5mm<br>Angle: 17° - 30° |
| Intended Use | Screw retained restoration | Screw retained restoration | Screw retained restoration |
| Material Composition | Ti 6Al 4V ELI(ASTM F136) | Ti 6Al 4V ELI(ASTM F136) | Ti 6Al 4V ELI(ASTM F136) |
| Surface Treatment | No | No | No |
| Sterile | No | No | No |

Substantial Equivalence Discussion

The subject Angled Abutment is substantially equivalent to the predicate devices in terms of indications for use and technical characteristics. The indications for use statement of the subject device is identical to our company's own reference device, K172630. In addition, the indications for use of the primary predicate, which states that it is "intended for use as an aid in prosthetic rehabilitation", is inherent to the overarching system.

They are made of the same material and have similar design. The size range of the predicate devices encompasses the size range of the subject device. The design is almost the same and there is not really any difference. Also, the test result of the fatigue test supported that the subject abutment would perform as well as the predicate devices.

**CCM Abutment & Multi CCM Abutment**

| | Subject Device | Primary Predicate Device |
|---|---|---|
| 510(K) Number | K200193 | K112045 |
| Device Name | Kisses Abutment System | SimpleLine II Abutment System |
| Manufacturer | Achimhai Medical Corporation | Dentium |
| Type | Internal | Internal |
| Indications for Use | The Kisses Abutment System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.<br><br>The Kisses Abutment System is for single and two stage surgical procedures. It is for delayed loading. | The SimpleLine II Abutment system is intended for use as an aid in prosthetic rehabilitation. |
| Principle of Operation | The abutments are to be coupled to the fixtures to make temporary or final prosthesis. | The abutments are to be coupled to the fixtures to make temporary or final prosthesis. |
| <CCM Abutment><br>Design & Size Range |  <br>Hex Non-Hex<br>Diameter: 4.0-4.5mm<br>Gingival Height: 1mm |  <br>Octa Non-Octa<br>Diameter: 4.8-6.5mm<br>Gingival Height: 1mm |
| Intended Use | Casting with Co Cr Mo (ASTM F1537) | Metal Casting restoration |
| Material Composition | Co Cr Mo(ASTM F1537) | Co Cr Mo(ASTM F1537) |
| Surface Treatment | No | No |
| Sterile | No | No |

| | Subject Device | Primary Predicate Device |
|---|---|---|
| 510(K) Number | K200193 | K161416 |
| Device Name | Kisses Abutment System | Multi Unit Abutment Plus |
| Manufacturer | Achimhai Medical Corporation | Nobel Biocare AB |
| Type | Internal | Internal |
| Indications for Use | The Kisses Abutment System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.<br><br>The Kisses Abutment System is for single and two stage surgical procedures. It is for delayed loading. | The Multi-unit Abutment Plus is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. |

| | | |
|---|---|---|
| Principle of Operation | The abutments are to be coupled to the fixtures to make temporary or final prosthesis. | The abutments are to be coupled to the fixtures to make temporary or final prosthesis. |
| <Multi CCM Abutment> Design & Size Range |  Diameter: 4.8mm |  Diameter: 4.8mm |
| Intended Use | Casting with Co Cr Mo (ASTM F1537) | Casting with dental gold alloy |
| Material Composition | Co Cr Mo(ASTM F1537) | Gold alloy |
| Surface Treatment | No | No |
| Sterile | No | No |

**Substantial Equivalence Discussion**

Kisses Plus Implant System is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. The intended use of the subject abutments remains identical to the company's own predicate device (K172630). In addition, the indications for use of the primary predicate (K072570), which states that it is "intended for use as an aid in prosthetic rehabilitation", is inherent to the overarching system.
They are made of the same material and have similar design. The size range of the predicate device encompasses the size range of the subject device. There are slight differences in design, however, it is very minor not affecting substantial equivalence.
We have performed the fatigue test to make sure the difference in design does not raise an issue in safety and effectiveness and also to make sure that the subject CCM abutments can be used with the identified compatible fixtures previously cleared (K142813 and K172630). The test result of the test supported substantial equivalence.
Based on the information and test results provided in submission, we conclude that the subject device is substantially equivalent to the predicate devices.

## 8. Non-Clinical Testing

- Fatigue test in accordance with ISO 14801
- Cytotoxicity, Sensitization, and Irritation tests per ISO 10993-5 and ISO 10993-10 were performed for this submission. In addition, biocompatibility testing is also being leveraged from the company's own previous clearance K172630.
- Steam sterilization validation in accordance with ISO 17665-1 and ISO 17665-2

We have performed the tests above to make sure the differences between the subject deice and the predicate device do not raise an issue in safety and effectiveness and the test result of the test supported substantial equivalence.

## 9. Conclusion

The subject devices and the predicate device have the same intended use and have the same technological characteristics.

Overall, the Kisses Plus Implant System has the following similarities to the predicate device:

* have the same intended use,
* use the same operating principle,
* incorporate the same design,
* incorporate the same material and the sterilization method.

Based on the similarities, we conclude that the Kisses Plus Implant System is substantially equivalent to the predicate devices.